

Mail Stop Interference
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

DAVID G. HEATH,
ARTHUR M. FRIEDLANDER, GEORGE W. ANDERSON,
and SUSAN L. WELKOS
Junior Party
(Application 08/699,716),

v.

RICHARD WILLIAM TITBALL,
ETHEL D. WILLIAMSON, SOPHIE E.C. LEARY,
PETRA C.F. OYSTON, and ALICE M. BENNETT
Senior Party
(Patent 5,985,285).

Patent Interference No. 105,564
(Technology Center 1600)

Before: FRED E. McKELVEY, *Senior Administrative Patent Judge*, and
RICHARD E. SCHAFER and SALLY GARDNER LANE, *Administrative Patent
Judges*.

LANE, *Administrative Patent Judge*.

Opinion Concurring filed by McKELVEY, *Senior Administrative Patent Judge*.

Decision – Interlocutory Motion – Bd.R. 125(b)

1 A joint motion for entry of a judgment of no interference-in-fact (Paper 20)
2 is before us. In an Order entered 22 June 2007, Heath was authorized to cancel
3 claims and the parties were authorized to file jointly a motion seeking a judgment
4 of no interference-in-fact. (Paper 20). The joint motion (Paper 21 ("Joint Motion"))
5 was filed with a "Proposed Amendment Contingent Upon Grant of Parties Joint
6 Motion For No Interference-In-Fact." (Exh. 2007). In the motion, the parties take
7 the position that, if Heath's proposed amendment is entered, then there will no
8 longer be an interference-in-fact.

9 The proposed amendment, seeks to cancel Heath claim 1 and amend the
10 remaining Heath claims that correspond to the count.

11 As further explained below, we only consider Heath's proposed
12 amendment to the extent it cancels Heath's claims since Heath was not
13 authorized to file a proposed amendment that amends the claims.¹ Thus, in the
14 Decision when we refer to "Heath's remaining claims", we are referring to the
15 claims that would remain if only that portion of the Heath amendment that
16 cancels claims was entered.

17 Thus, we have considered the parties' arguments set out in the Joint
18 Motion as they relate to Heath's remaining claims. We determine that the parties

¹ Nor would Heath have been authorized to file a motion proposing to amend claims. (See Standing Order (SO) at 208.5.2 stating that amendment of claims is not permitted but that a party may cancel or add a claim as provided herein). Furthermore, Heath would not have been authorized to add a claim and then assert that such claim does not correspond to the Count. (SO at 208.5.1).

1 have not shown that there is no interference-in-fact between Heath's remaining
2 claims and the Titball claims.²

3 The motion for no interference-in-fact is **DENIED** and the proposed
4 amendment will not be entered.

5 Facts

6
7 1. The interference was declared on 4 May 2007 between Heath's
8 08/699,716 ('716) application and Titball's 5,985,285 ('285) patent.

9 2. The real party-in-interest for junior party Heath is said to be the
10 United States Army. (Paper 6).

11 3. The real parties-in-interest for senior party Titball are said to be the
12 Secretary of State for Defense, Defense Science and Technology Laboratory,
13 Great Britain and Avecia Limited as licensee. (Paper 11).

14 4. The parties were authorized to file the Joint Motion and Heath was
15 authorized to file a contingent proposed amendment canceling certain Heath
16 claims. (Paper 20).

17 5. The Decision of June 22, 2007, stated that "Heath has agreed to
18 cancel its 'vaccine claims' and the parties agreed that, once such claims are
19 cancelled, there will be no interference-in-fact." (Paper 20 at p. 2, ll. 9-11).

20 6. In the Decision, it was "ORDERED that the Heath motion for
21 authorization to file a motion for no interference-in-fact in response to the Order
22 to Show Cause (Paper 4) is GRANTED; FURTHER ORDERED that Titball may

² Moreover, as further discussed below, we make an observation that the parties have not shown that the claims as Heath proposes to amend them would not interfere-in-fact with the Titball claims.

1 join in the motion for no interference-in-fact and that Heath may agree to cancel
2 involved claims as part of the motion . . .” (*Id.* at p. 3, ll. 13-18).

3 7. In the Joint Motion, the parties asserted:

4 The statement “Heath has agreed to cancel its ‘vaccine claims’ and
5 the parties agree that, once such claims are canceled, there will be
6 no interference-in-fact” is not precisely what the parties indicated
7 that they had agreed to during the June 19, 2007 telephone
8 conference with the APJ. The record requires correction in that
9 regard. The parties agreed that, concurrently with the filing of the
10 motion for no interference-in-fact, party Heath would simultaneously
11 submit an Amendment to the ‘716 application canceling Heath
12 claim 1, amending Heath claim 2 to be independent, and amending
13 or canceling other Heath claims corresponding to the count so as to
14 be consistent with the cancellation of claim 1 and limitation to the
15 subject matter of claim 2. Pursuant to that indication, party Heath
16 submits herewith its Proposed Amendment Contingent upon Grant
17 of Parties’ Joint Motion for No Interference-In-Fact (Exhibit 2007) in
18 which Heath claim 1 is canceled, along with Heath claims 4, 6 and
19 18-30, and other claims are amended to be consistent with claim 2
20 which has been placed in independent form.

21
22 (Joint Motion at p. 3, ll. 1-4).

23 8. The Count is claim 13 of the Heath application or claim 17 of the
24 ‘285 patent. (Paper 1 at 4).

25 9. The subject matter of the count is:

26 a host cell transformed with a recombinant DNA construct comprising: (i) a
27 vector, and (ii) a F1-V DNA fragment which encodes all F1 capsular antigen of
28 *Yersinia pestis* and all of V antigen of *Yersinia pestis* [Heath claim 13]

29 or

30 a vaccine consisting essentially of isolated or purified recombinant *Yersinia*
31 *pestis* V antigen and *Yersinia pestis* F1 antigen, or a protective epitopic part of
32 each of these in a form other than whole *Yersinia pestis* organisms,

33 wherein the vaccine is a live vaccine comprising gut colonizing organisms
34 that have been transformed using recombinant DNA to enable them to express a
35 fusion protein comprising both V and F1 antigen amino acid sequences or a
36 protective epitopic part of each. [‘285 claim 17].

37

1 10. Heath claims 1, 2, 7, 9, 10, and 12-17 and Titball claims 1-4, 8-17,
2 21-31, 36, 42, 43, and 48 are designated as corresponding to the Count. (Paper
3 1 at 4).

4 11. If that portion of Heath's proposed amendment that cancels claims
5 is entered, Heath's remaining claims would be claims 2, 3, 5, 7-17, and 31.

6 12. Heath claims 13 (unamended) is as follows:
7 A host cell transformed with a recombinant DNA construct comprising:
8 (i) a vector, and
9 (ii) a F1-V DNA fragment which encodes all F1 capsular antigen of
10 *Yersinia pestis* and all of V antigen of *Yersinia pestis*.

11 13. Titball's claim 16, when recited in light of the claims on which it
12 depends, provides:
13 A vaccine consisting essentially of isolated or purified recombinant *Yesinia*
14 *pestis* V antigen and *Yersinia pestis* F1 antigen or a protective epitopic
15 part of each of these in a form other than whole *Yersinia pestis* organisms,
16
17 wherein the vaccine is a live vaccine, and
18
19 wherein the live vaccine comprises human or animal gut colonising
20 organisms that have been transformed using recombinant DNA to enable
21 them to express one or both of V antigen and F1 antigen.
22

23 14. Thus, each of the Titball claims is directed to a vaccine or a method
24 of protecting a human or animal body against the effects of *Y. pestis*, by
25 providing a protective immunological activity.

26 15. The parties assert that none of Heath's claims (including claim 13)
27 necessitate any protective immunological activity. (Joint Motion at 7-8).

1 16. Because of this difference, the parties assert that the subject matter
2 of the remaining Heath claims does not anticipate or render obvious any of the
3 subject matter of the Titball claims. (Joint Motion at 8).

4 17. The parties assert that none of the remaining claims of Heath would
5 anticipate any of the method claims of Titball "at least in part because nothing in
6 the involved Heath claims would teach the administration step required by the
7 Titball method of protection claims." (Joint Motion at 9).

8 18. The parties also assert that "[n]othing in any of the involved Heath
9 claims set forth in the Proposed Amendment would explicitly teach or in any way
10 necessitate [protective immunological] activity." (Joint Motion at 10).

11 19. In regard to obviousness, the parties make the following argument:
12 Use of this DNA fragment [as claimed in Heath claim 2] (or recombinant
13 construct comprising same (Heath claim 7) or host cell transformed with
14 such a construct (Heath claim 13)) to protect a human or animal body from
15 the effects of infection with *Y. pestis* (as required by the involved Titball
16 method claims) would not have been obvious to one of ordinary skill in the
17 art. (MF 56). That is, one of ordinary skill in the art would not have been
18 motivated to use the DNA fragment (recombinant construct or transformed
19 host cell) as a DNA or genetic vaccine with any reasonable expectation of
20 success. (MF 57).
21
22 (Joint Motion at 11-12).

23 20. To support this argument, the parties assert that "[t]he DNA and
24 genetic vaccine art was unpredictable at the time of the invention," indicating that
25 one of ordinary skill would have had no basis for anticipating or predicting
26 success in administering either the DNA fragment of Heath claim 2, the
27 recombinant construct of Heath claim 7, or the transformed host cell of Heath
28 claim 13 to achieve protection in a body from the effects of infection with *Y.*
29 *pestis*. (Joint Motion at 12).

1 21. Heath's specification, though, discusses use of the disclosed DNA
2 sequences incorporated into a vector or in a viral or bacterial host, wherein:

3 It is another object of the invention to provide a recombinant vector
4 comprising a vector and the above described DNA fragment for use
5 as a DNA vaccine.

6
7 It is a further object of the present invention to provide a host cell
8 transformed with any of the above-described recombinant DNA
9 constructs for use as a live bacterial vaccine when the host cell is a
10 bacteria such as Salmonella, BCG, or a live viral vaccine when the
11 host cell is a virus such as adenovirus, Venezuelan Equine
12 Encephalitis virus. These transformed cells, bacteria and viruses
13 can also be used as a source for the *Y. pestis* F1-V protein.

14
15 (Heath Specification at p. 6, ll. 1-8).

16 22. Heath's specification also provides: "In another embodiment, the
17 present invention relates to a DNA sequence incorporated into a vector which
18 can be used as a DNA vaccine in animals, including humans, or which can be
19 used in a live bacterial or viral vaccine, e.g. Salmonella, BCG, adenovirus, or
20 Venezuelan Equine Encephalitis virus." (Heath Specification at p. 10, ll. 14-17).

21 23. The parties rely on the affidavit of Robert G. Ulrich, M.D., to support
22 their assertions.

23 24. Dr. Robert G. Ulrich identifies himself as the Chief of the
24 Department of Immunology of the United States Army Medical Research Institute
25 of Infectious Diseases. (Exh. 2001 at ¶ 3 and Exh. 2002).

26 25. Dr. Ulrich testified that he has "extensive experience in the field of
27 immunology including DNA and genetic vaccines." (Exh. 2001 at ¶ 4).

28 26. Dr. Ulrich considered one of ordinary skill in the art to be one who
29 had at least a master's degree in biochemistry and/or immunology and had the
30 basic skills in vaccine formulation. (Exh. 2001 at ¶ 6).

1 27. Dr. Ulrich stated that based on his review of a number of journal
2 articles, it is his opinion that "one skilled in the art could not reasonably believe
3 that a given DNA fragment encoding F1 and V antigens could be used
4 successfully as a vaccine such that it produces a protective immunological
5 response." (Exh. 2001 at ¶ 7).

6 28. In addition, Dr. Ulrich testified that he had reviewed prior art cited
7 during the prosecution of the involved application and patent. (Exh. 2001 at
8 ¶ 11).

9 29. Dr. Ulrich testified that the cited art "at most, discloses a live
10 vaccine directed to F1 antigen or V antigen, but not both" and that
11 a DNA fragment or construct encoding *both* F1 and V antigens is
12 significantly different from a DNA fragment or construct encoding
13 only one antigen or a DNA fragment or construct encoding V
14 antigen and protein A such that one skilled in the art would not
15 assume, with a reasonable likelihood of success, that the DNA
16 fragment or construct encoding *both* F1 and V antigens would
17 result in properly presented antigenic epitopes when administered
18 to a subject in order to confer a protective immunological response.
19
20 (Exh. 2001 at ¶ 12).

21 30. Dr. Ulrich testified that as of the date of his affidavit, he knew of no
22 other prior art that would be material to the patentability of the involved Titball
23 claims. (Exh. 2001 at ¶ 19).

24 31. Dr. Ulrich concluded that one skilled in the art would not have
25 reasonably expected that the DNA fragments, constructs and host cells disclosed
26 in Heath could have been used as a vaccine given the state of the art at the time.
27 (Exh. 2001 at ¶ 15).

32. In regard to the discussion of DNA and live vaccines in the Heath specification, Dr. Ulrich testified:

Although, the specification of the '716 application recites that the disclosed DNA fragments, DNA constructs, and host cells may be used as a vaccine (see, for example, page 6, lines 1-9), it is my opinion that since there is no disclosure that the disclosed DNA fragments, DNA constructs, and host cells were administered to a subject and resulted in an immunological response and the overall failure of DNA and genetic vaccines at the time (as set forth above), one skilled in the art could not have reasonably expected that the DNA fragments, DNA constructs, and host cells may be used as a vaccine with a reasonable likelihood of success.

In fact, in my opinion, the failures, e.g. severe side effects, of the live plague vaccines at the time of the invention, i.e. EV76, teach away from the use of live vaccines. Thus, although the '716 application recites that the disclosed host cells may be used as a live vaccine, in view of the side effects of EV76 and the fact that the '716 application does not provide any actual experiments evidencing the feasibility of administering the host cells as live vaccines and the disclosure of Burrows & Bacon (1957), Leary (1995) and Williamson et al (1995), it is my opinion that one skilled in the art would not be motivated to administer a host cell according to the '716 application with a reasonable likelihood of success.

It is my opinion that, one of ordinary skill in the art would not have had a reasonable expectation of success in providing a protective immunological response by administering the DNA fragments, DNA constructs and host cells in the '716 application as a vaccine in view of the overall failure of DNA and genetic vaccines and the cited art which teach away from such.

(Exh. 2001, at ¶ 15-17).

Discussion

As the movants, Titball and Heath have the burden of establishing that they are entitled to the relief requested, Bd.R. 121(b), that is a judgment that there is no interference-in-fact between the involved Heath claims and the involved Titball claims. (Joint Motion at p. 2, ll. 2-5). This burden remains with the

1 movants even though the motion is unopposed. *GN v. SW*, 57 USPQ2d 1073,
2 1076 (BPAI 2000).

3 The parties must shoulder this burden within the orders provided on June
4 22, 2007, in Paper 20. Those orders expressly provided for Heath to propose an
5 amendment canceling "vaccine claims" with the intention that the parties would
6 then be able to demonstrate no interference-in-fact. (FF 5 and 6). The parties
7 now contest these orders and have taken it upon themselves to create their own
8 order to amend claims involved in this Interference. (FF 7).

9 "The action of the Patent and Trademark Office will be based exclusively
10 on the written record in the Office. No attention will be paid to any alleged oral
11 promise, stipulation, or understanding in relation to which there is a disagreement
12 or doubt." 37 C.F.R. § 1.2. Thus, if the parties did not agree with the recollection
13 of the Heath's agreement to cancel "vaccine claims" memorialized in the written
14 Decision, the proper course of action would have been to request a conference
15 call with the APJ for clarification and issuance of a new Decision and orders
16 consistent with a mutual understanding. Accordingly, in the absence of any order
17 authorizing amendments to involved claims, we disregard the proposed
18 amendment beyond the cancellation of claims and proceed to analyze
19 interference-in-fact of the remaining claims, unamended. (See fn. 1, *supra*).

20 "An interference exists if the subject matter of a claim of one party would,
21 if prior art, have anticipated or rendered obvious the subject matter of a claim, of
22 the opposing party and vice versa." 37 C.F.R. § 41.203(a); *see also Eli Lilly and*
23 *Co. v. Board of Regents of the University of Washington*, 334 F.3d 1264 (Fed.
24 Cir. 2003). Thus, in order to show that there is no interference-in-fact, the parties

1 must show that either the remaining claims of Heath do not anticipate or render
2 obvious the claims of Titball or that the claims of Titball do not anticipate or
3 render obvious the remaining claims of Heath. To this end, the parties assert
4 that the Heath claims do not anticipate the Titball claims, nor render them
5 obvious.

6 A claim in an interference is given its broadest reasonable construction in
7 light of the specification of the application or patent in which it appears.
8 37 C.F.R. § 41.200(b) (2006). Thus, while we look to the specification to
9 understand the scope of a given claim, we are mindful that “limitations of the
10 specification [should not be] read into a claim where no express statement of the
11 limitation is included in the claim.” *In re Prater*, 415 F.2d 1393, 1404-05 (CCPA
12 1969).

13 To anticipate a claim, the prior art reference must disclose each and every
14 element of the claim. *Verdegaal Bros., Inc. v. Union Oil Co. of California*, 814
15 F.2d 628, 631 (Fed. Cir. 1987). A particular species may be anticipated by
16 disclosure of a limited genus even though the species is not specifically
17 disclosed. *Bristol-Myers Squibb Co. v. Ben Venue Labs, Inc.*, 246 F.3d 1368,
18 1380 (Fed. Cir. 2001) (“[T]he disclosure of a small genus may anticipate the
19 species of that genus even if the species are not themselves recited.”).

20 A claim can be rendered obvious when “[c]ommon sense teaches . . . that
21 familiar items may have obvious uses beyond their primary purposes.” *KSR Int’l*
22 *Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1742 (2007). When prior art recites a broad
23 genus, it may render a narrower species encompassed by it obvious. *See Merck*
24 *& Co. v. Biocraft Labs., Inc.*, 874 F.2d 804, 807 (Fed. Cir. 1989) (“That the [prior

1 art] patent discloses a multitude of effective combinations does not render any
2 particular formulation less obvious. This is especially true because the claimed
3 composition is used for the identical purpose taught by the prior art.”).

4 Titball’s claim 16, when recited in light of the claims on which it depends,
5 provides:

6 A vaccine consisting essentially of isolated or purified recombinant *Yersinia*
7 *pestis* V antigen and *Yersinia pestis* F1 antigen or a protective epitopic
8 part of each of these in a form other than whole *Yersinia pestis* organisms,
9

10 wherein the vaccine is a live vaccine, and
11

12 wherein the live vaccine comprises human or animal gut colonising
13 organisms that have been transformed using recombinant DNA to enable
14 them to express one or both of V antigen and F1 antigen.
15

16 (FF 13). Briefly stated, Titball claims a live vaccine comprising an organism
17 transformed with recombinant DNA that expresses V and F1 antigens.

18 In agreement with the parties, we construe the term “vaccine” in Titball’s
19 claims to be a composition that exhibits protective immunological activity. (Joint
20 Motion at 10, MF 48). Thus, Titball claims a transformed host cell that expresses
21 the F1 and V antigens and that provides a protective immunological activity.

22 Turning to Heath’s claims, we disagree with the parties that Heath does
23 not claim a composition that provides a protective immunological activity. Heath
24 claim 13³ recites:

25 A host cell transformed with a recombinant DNA construct comprising:

26 (i) a vector, and

³ For reasons discussed above, we have not considered that portion of the Heath proposed amendment that amends claim 13 in rendering our decision. Thus, our decision is based upon current and unamended claim 13.

1 (ii) a F1-V DNA fragment which encodes all F1 capsular antigen of
2 *Yersinia pestis* and all of V antigen of *Yersinia pestis*.
3 (FF 12).

4 Though the term "vaccine" is not included in Heath's claim, when we look
5 to Heath's specification to understand the full scope of its claim, i.e., to give the
6 claims their broadest reasonable construction, we find the following:

7 It is another object of the invention to provide a recombinant vector
8 comprising a vector and the above described DNA fragment **for**
9 **use as a DNA vaccine**.

10
11 It is a further object of the present invention to provide a host cell
12 transformed with any of the above-described recombinant DNA
13 constructs **for use as a live bacterial vaccine** when the host cell is
14 a bacteria such as Salmonella, BCG, or a live viral vaccine when
15 the host cell is a virus such as adenovirus, or Venezuelan Equine
16 Encephalitis virus. These transformed cells, bacteria and viruses
17 can also be used as a source for the *Y. pestis* F1-V protein.

18
19 (Heath Specification at p. 6, ll. 1-8; FF 21) (emphasis added). As shown by its
20 specification, Heath contemplates use of DNA fragments, recombinant DNA
21 constructs, and transformed host cells as vaccines that provide protective
22 immunological activity. Thus, one skilled in the art reading the Heath
23 specification would have understood the subject matter of at least Heath claim 13
24 to include a vaccine. Accordingly, in light of Heath's specification, and giving its
25 claims the broadest reasonable construction, we construe the remaining Heath
26 claims to encompass vaccines against *Y. pestis*.⁴

⁴ The broadest reasonable construction of the claims includes vaccines, but is not limited to them. We note that Heath provides other uses of the claimed DNA, recombinant constructs, and transformed host cells in its specification and these are not necessarily excluded from the construction we have adopted.

1 The parties have argued (relying upon Dr. Ulrich's testimony), essentially,
2 that the vaccines claimed by Heath, in light of its proposed amendment, would
3 not be expected to be functional by those in art at the time Heath filed its
4 application. Whether or not claims are enabled is not of concern in determining if
5 the parties claim interfering subject matter under 37 C.F.R. § 41.203(a).
6 Moreover, it does not appear that Dr. Ulrich necessarily understood that an
7 interference might exist as to vaccines, because (and we do not find it
8 unexpected) Dr. Ulrich probably does not, and would not be expected to,
9 understand the principle of law that claims in an interference are given their
10 broadest reasonable interpretation or that a generic claim encompasses
11 numerous species (e.g., a broad claim can cover a vaccine even if it covers
12 alternative embodiments).

13 Comparison of Heath's claim 13 and Titball's claim 16 reveals that each is
14 directed to subject matter including a vaccine comprising a host cell that is
15 transformed with a recombinant DNA vector that encodes the F1 and V proteins.
16 Accordingly, even if Heath canceled its claim 1 as proposed, both Heath and
17 Titball will have claims that include subject matter (vaccines) that would
18 anticipate, or alternatively, have rendered obvious, the other's claims and,
19 therefore, their claims present interfering subject matter at least to the extent that
20 both cover vaccines. The parties have failed to show that there is no
21 interference-in-fact.

22 Observation

23 In coming to our decision, we did not consider Heath's claims as proposed
24 to be amended by the Heath amendment, i.e., the proposed amended claims.

1 However, for purposes of any future prosecution of these proposed amended
2 claims, we observe that even if we had considered these claims, we would not
3 have held that there is no interference-in-fact. That is, even if Heath's claims
4 were limited to recombinant DNA constructs and host cells transformed with a
5 recombinant DNA construct, wherein the recombinant DNA construct encodes a
6 fusion protein of the F1 capsular antigen and the V antigen, Heath's specification
7 still contemplates use of these recombinant DNA constructs and transformed
8 host cells as vaccines that provide protective immunological activity. (FF 21).
9 Those skilled in the art reading the Heath specification would have understood
10 the claimed subject matter to include a vaccine and, accordingly, we would
11 construe the Heath claims, as proposed to be amended, to encompass vaccines
12 against *Y. pestis*. Because both parties' claimed subject matter would
13 encompass vaccines,⁵ we would find that the parties had failed to show no
14 interference-in-fact.
15

⁵ See Titball claim 17.

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Order

Upon consideration of the record and for reasons given, it is

ORDERED that the Joint Motion seeking a judgment of no
interference-in-fact is DENIED; and

FURTHER ORDERED that the Heath proposed amendment shall not be
entered.

/Richard E. Schafer/)
RICHARD E. SCHAFER)
Administrative Patent Judge)
_____)
/Sally Gardner Lane /)
SALLY GARDNER LANE_____)
Administrative Patent Judge)

1 McKelvey, *Senior Administrative Patent Judge*, concurring.

2 The majority holds that there is no interference-in-fact. I agree and
3 therefore concur in the result—the "bottom line" being entry of judgment against
4 Heath assignor to the United States of America as represented by the United
5 States Army.

6 I write separately because the rationale of the majority gives me pause.

7 **A. Motions authorized**

8 The parties were authorized to file a joint motion for judgment based on an
9 alleged no interference-in-fact.

10 Heath was given leave to file a motion for leave to enter an amendment
11 canceling claims. But, the Heath amendment requests both (1) cancellation of
12 claims corresponding to the count and (2) amendment of other claims
13 corresponding to the count. Heath was not authorized to file an amendment to
14 amend claims corresponding to the count.

15 **B. The amendments**

16 As a general proposition, during an interference if a party "cancels" a
17 claim corresponding to a count, judgment is entered against that party as to the
18 cancelled claim. Interference practice is not *ex parte* prosecution where claims
19 can be cancelled or amended at the will of the applicant. Once a claim is
20 "involved" in the interference it cannot be cancelled without a consequence. The
21 famous "Please cancel claim 1 *without prejudice*." often used during *ex parte*
22 prosecution is not part of interference practice. When a claim *corresponding to*
23 *a count* is cancelled, judgment is entered against that claim. Judgment is
24 necessary to invoke the estoppel provisions of 37 C.F.R. § 41.127(a) (2007).

1 Nor does interference practice permit "amendment" of a claim. Rather, a
2 party seeking to "amend" a claim may (1) cancel the claim sought to be
3 "amended" and (2) add a new claim. Each claim will have a different claim
4 number. By not having amended claims in an interference, any judgment issued
5 cannot be ambiguous. A reference to a claim becomes certain.

6 Lastly, one cannot "avoid" or "get out of" an interference through skillful
7 claim "amendment." If a party believes there is no interference-in-fact between
8 (a) the subject matter of its involved claims and (b) the subject matter of an
9 opponent's involved claims, then the party should file a motion for judgment
10 based on no interference-in-fact. If the motion is granted, the party "keeps" its
11 claims and the opponent "keeps" its claims. The respective sets of claims define
12 subject matter which is patentably distinct.

13 The majority does not enter the proposed amendment filed by Heath.
14 Although I would not have authorized the amendment in the first place, since the
15 amendment is not being entered, I concur with its non-entry.

16 The majority declines to enter the amendment because Heath did more
17 than what the judge assigned to the interference authorized. Heath sought
18 cancellation and amendment of claims. Although I would not have authorized
19 cancellation of any Heath claim, the judge authorized only cancellation—not any
20 amendment. Heath now maintains that discussion during a conference call was
21 understood to authorize both cancellation and amendment. But, the written order
22 issued by the judge after the conference call only authorized cancellation. If
23 Heath had a "beef" with the written order, Heath should have scheduled another
24 conference call for clarification. Having not asked for a follow-up conference

1 call, Heath cannot wait until filing the amendment to ask for amendment of claims
2 as well as cancellation of claims.

3 **C. Interference-in-fact**

4 There is a possibility that I do not fully understand the technology involved
5 in this interference. The parties certainly have not presented an understandable
6 tutorial.

7 Notwithstanding my possible lack of technical knowledge in this field, here
8 is what I understand the facts to be.

9 1. Heath composition claims corresponding to the count, and
10 therefore "involved" in the interference within the meaning of 35 U.S.C. § 135(a),
11 are generic claims which "cover," but are not limited to any "specific vaccine."

12 2. Titball composition claims corresponding to the count cover and
13 are limited to a "specific vaccine."

14 3. Both Heath and Titball describe in their respective specification
15 the "specific vaccine."

16 An interference-in-fact exists when the claim of one party would, if prior
17 art, have anticipated or rendered obvious the subject matter of a claim of the
18 opposing party and vice versa. See 37 C.F.R. § 41.203(a) (2007), codifying the
19 PTO's interpretation of former 37 C.F.R. § 1.601(j) (2003), an interpretation which
20 survived judicial scrutiny in *Eli Lilly and Co. v. Board of Regents of the University*
21 *of Washington*, 334 F.3d 1264 (Fed. Cir. 2003).

22 In *Eli Lilly*, one party claimed a genus and the opponent claimed a specific
23 species. The party *did not* describe the specific species in its application. The
24 difference between *Eli Lilly* and this case manifests itself immediately. Here

1 Heath describes the "specific species" described and claimed by Titball. So,
2 whereas an interference on the specific species would not have been possible in
3 *Eli Lilly*, here an interference on the "specific vaccine" is a foregone conclusion.

4 In retrospect, the interference probably should have been declared with a
5 "specific vaccine" count. Alternatively, the Board *sua sponte* could have
6 redeclared the interference with a "specific vaccine" count after the conference
7 call. But, neither event happened. Any "failure" on the part of the Board to
8 conduct the interference with a "specific vaccine" count does not excuse Heath
9 from seeking to refine the interference. Neither party sought to substitute a
10 "specific vaccine" count for the present count. Rather, Heath (and probably
11 Titball) apparently believe if Heath can eliminate the "specific vaccine" from the
12 Heath claims, then there is no interference in fact.

13 Heath was put under an order to show cause because it could not
14 establish priority based on the "generic" count. Heath's response was to
15 "confess and avoid." It goes something like this: "I confess I can't establish
16 priority on the specific vaccine or any other embodiment within the scope of the
17 count, but I want to avoid a judgment on my broad claims."

18 In response to the order to show cause, Heath should have (1) moved to
19 substitute a narrow "specific vaccine" count and (2) agreed to entry of judgment
20 on the specific vaccine count. Upon return to *ex-parte* prosecution, Heath (a) can
21 amend its claims to exclude the "specific vaccine" and (b) maintain before the
22 Examiner that its amended claims define subject matter which would not have
23 been anticipated or rendered obvious over the subject matter of the "specific
24 vaccine" count. See *In re Deckler*, 977 F.2d 1449 (Fed. Cir. 1992) (party losing

1 interference is not entitled to claims to same patentable invention as count--
2 based on estoppel) and *compare* (1) *In re Yale*, 347 F.2d 995 (CCPA 1965) and
3 (2) *In re Johnson*, 558 F.2d 1008 (CCPA 1977).

4 A claim in an interference is given its broadest reasonable interpretation.
5 37 C.F.R. § 41.200(b) (2007). While a limitation from the specification is not to
6 be imported into the claim, the specification may be used to interpret what the
7 claims covers and its scope.

8 A proper interpretation of the Heath claims reveals that among other
9 things Heath intends to "cover" the vaccines described in its specification. One
10 of those vaccines is the "specific vaccine" described and claimed by Titball. The
11 subject matter of the Titball claim "anticipates" (using a 35 U.S.C. § 102(b)
12 anticipation test) the subject matter of the Heath claim. The Heath claim, to the
13 extent it "covers" at least one specific vaccine described in the Heath
14 specification (which is the same as the specific vaccine described and claimed by
15 Titball) anticipates the subject matter of the Titball claims. There is, accordingly,
16 an interference-in-fact with respect to at least the "specific vaccine." The party
17 who is *not* first to invent is not entitled to claims which "cover" the "specific
18 vaccine" even if that party is first to invent a patentably distinct generic or species
19 invention. See *In re Saunders*, 219 F.2d 455 (CCPA 1955).

20 For the reasons given, it is my view that (1) there is an interference-in-fact,
21 (2) the parties, and in particular Heath, have not sustained their burden of
22 showing that there is no interference-in-fact, (3) the motion for judgment based
23 on no interference-in-fact should be denied, (4) as a result Heath has not
24 overcome the order to show cause, and (4) therefore judgment should be

1 entered against Heath. Whether Heath is entitled to other claims is a matter to
2 be resolved upon resumption of *ex parte* prosecution. In any future *ex parte*
3 examination, the Examiner may properly consider an estoppel based on the
4 failure of Heath to redefine the interference with a narrower count. 37 C.F.R.
5 § 41.127(a) (2007).

/Fred E. McKelvey/
FRED E. McKELVEY
Senior Administrative Judge

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